K002221

AUG - 9 2000

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2. 510(k) SUMMARY of Safety and Effectiveness

Heinz Kurz GmbH Medizintechnik

As required by Section 807.92(c)

2.1 Submitter: [807.92 (a)(1)]

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Germany — eMail tkurz@kurzmed.de
usteinhardt@kurzmed.de

2.2 Contact Person: [807.92 (a)(1)]

Dagmar S. Mäser
Business Support International
Amstel 320-I — Tel. +31-20-428 95 91
1017 AP Amsterdam — Fax +31-20-428 94 29
The Netherlands — eMail bsi@xs4all.nl

2.3 Date Summary Prepared: [807.92 (a)(1)]

July 14, 2000

2.4 Device Names: [807.92 (a)(2)]

Proprietary	K-Piston Titanium Stapedial Prosthesis
Common	Middle Ear Piston
Classification	Middle Ear Prosthesis, Partial Ossicular Replacement
Product Code	77 ETB
Regulation #	CFR 874.3450

2.5 Reason for Submission:

Material and design change of previously cleared device (s. 2.6, 2.7, 2.8, 2.12 and Comparison Table 2.13).

2.6 Modification to Existing Device: [807.92 (a)(3)]

K 973356 K-Piston with Band Hook (Pure Gold)

2.7 Device Description: [807.92(a)(4)+(6)]

KURZ titanium K-Pistons consist of a piston with a slightly tilted band loop that ends in a hooklet-like process.

The titanium pistons are substantially equivalent to the previously cleared gold devices with the following exceptions:

1. Material: ASTM F 67 Titanium instead of Pure Gold
2. Design: The loop is attached to the smoothly rounded piston with a straight 0.2 mm shaft, while the transition between the one-piece gold piston and its loop segments is wedge-shaped.

The indications for use, piston diameters, loop size and thickness, and available lengths are identical.

✓ No change in indications for use

2.8 Reasons for Device Modification: [807.92 (d)]

Material:

1. Titanium provides excellent sound conduction even at higher frequencies;
2. Due to its lower specific weight[1] the device is substantially lighter than the gold piston;
3. Due to special processes used in the manufacture of titanium pistons, identical ease of handling and pliability of the loop could be achieved.

Design

The design modifications have production-technical reasons and do not affect the safety and effectiveness when comparing titanium with the previously cleared gold K-Pistons:

1. Due to its specific material properties, titanium cannot be shaped like gold.[2] The two diameter pistons (0.4 + 0.6 mm) are therefore laser-welded to the 0.2 mm stem bearing the loop.
2. Subsequently, the devices are treated thermally in a special manufacturer-developed process resulting in the recrystallization of the shaped and hardened loop parts. The effect of this process is that the

[1] Gold: 19.3 kg/dm^3; Titanium: 4.5 kg/dm^3

[2] Gold K-Pistons are wrought or shaped of a single piece of material.

loop parts become almost as pliant as those of the gold pistons.

2.9 Intended Use: [807.92 (a)(5)]

For bridging the stapes in case of otosclerosis and for bridging defects of the ossicular chain between manubrium mallei and vestibulum (malleovestibulopexy).

The device is intended for the exclusive use by qualified medical personnel trained in the bridging of partial auditory ossicle defects.

2.10 Industry Standards: [807.92 (d)]

KURZ certifies compliance with required ISO/EN/ASTM/ AAMI/ANSI and other device-related standards that apply to the manufacture, packaging, labeling, sterilization, and reprocessing (custom instruments) of subject devices including the validation of these processes.

2.11 MRI Environment: [807.92 (d)]

Testing in a 0.5 Tesla nuclear magnetic resonance (NMR) tomograph has revealed no implant movement and no adverse tissue effects attributable to MRI-generated heating. The image quality may be impeded or blurred in direct vicinity of the implant. To date, no report of hearing loss or other adverse effect has come to the attention of the manufacturer. KURZ recommends strict adherence to the instructions for the use of magnetic resonance imaging tomographs.

2.12 Information Bearing on the Safety and Effectiveness: [807.92 (b)(3)]

The KURZ K-Piston Titanium Stapedial Prostheses have the same intended use as the previously cleared devices made of pure gold. With the exception of the described material and design changes, there are no additional characteristics known that should adversely affect the safety and effectiveness of these implants.

The results of design validation raise no new issues of safety and effectiveness.

2.13 KURZ K-Piston Titanium Stapedial Prosthesis

C O M P A R I S O N of DESIGN + SAFETY and EFFECTIVENESS

Device	Titanium K-Piston	Gold K-Piston
Catalog #	1006 103 – 1006 170	1005 103 – 1005 170
Intended Use	Bridging the stapes in case of otosclerosis and defects of the ossicular chain between manubrium and vestibulum (malleovestibulopexy)	Bridging the stapes in case of otosclerosis and defects of the ossicular chain between manubrium and vestibulum (malleovestibulopexy)
Model #	14	14
Dimensions – Length	3.50 – 6.00 mm (0.25 mm intervals) 6.00 – 10.00 mm (1.00 mm intervals)	3.50 – 6.00 mm (0.25 mm intervals) 6.00 – 10.00 mm (1.00 mm intervals)
- Loop Shaft Ø	0.2 mm	Gradually tapered from piston diameter to loop width
- Piston Ø	0.4 mm + 0.6 mm	0.4 mm + 0.6 mm
- Loop Band Width	0.3 mm	0.3 mm
- Loop Ø	1.0 mm	1.0 mm
Material	ASTM F67 Titanium	Pure Gold
Single Use	Yes	Yes
Sterile	Yes	Yes
Design Comparison	The laterally displaced band loop is attached to the piston by means of a 0.2 mm shaft that is seamlessly laser-welded to the smoothly rounded piston stem (0.4 + 0.6 mm)	The transition of the piston stem (0.4 + 0.6 mm) gradually tapers to the width of the laterially displaced band loop. The device is wrought of a single piece of gold
Loop Pliability	Substantially Equivalent	Substantially Equivalent
Safety & Effectiveness of Design Change [807.92 (b)(1)]	Tensile strength tests at approx. seven times the middle ear forces acting on the implant have proven the stability of the lasered connection between the piston and the loop shaft. The implant is as safe and effective as the previously cleared gold K-Piston. *Careful attention is to be paid to KURZ instructions.*	
Custom Accessory	KURZ Measuring Rod, Cat. # 8000 106	KURZ Measuring Rod, Cat. # 8000 106

Heinz Kurz G.m.b.H.
Medizintechnik
Tübinger Straße 3
72144 Dusslingen

Signature _____ Date July 17, 2000

Uwe Steinhardt
Technical Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 2000

Mr. Dagmar S. Mäser
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K002221
Trade Name: Kurkz K-Piston Titanium Stapedial Prosthesis, Model 1006
Regulatory Class: II
Product Code: 77ETB
Dated: July 21, 2000
Received: July 24, 2000

Dear Mr. Mäser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number K002221

Device Name **K-Piston Titanium Stapedial Prosthesis**

INDICATIONS FOR USE

1. For bridging the stapes in case of otosclerosis;
2. For bridging defects of the ossicular chain between manubrium mallei and vestibulum (malleovestibulopexy)

Description of Implant and Intended Situs

The titanium prosthesis consists of a piston with a laterally displaced band loop ending in a hooklet-like process. The band loop is attached to the long incudal process or, in case of malleovestibulopexy, at the manubrium mallei. The piston enters into the opened perilymphatic space.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

(Per CFR 801 109)

(Optional Format 1-2-96)

Karen H Baker

(Division Sign-Off)
Division of Ophthalmic Devices
(b) Number K002221